

Claims 1, 2, 10, 11, 12, 14, 15 and 19 stand rejected under 3 U.S.C 102(b) as being anticipated by Suzuki et al., U.S. Patent No. 4,292,299.

In response to the examiners 102 (b) rejection of claims 1, 2, 10, 11, 12, 14, 15 and 19, the examiner is incorrect that the present invention was patented or described by Suzuki.

Suzuki et al. discloses a medical preparation composed of an adhesive layer and a non-adhesive layer, with at least one of the layers made to contain a medicament ('299 claim 1 and column 1 lines 60-68 to column 2 line 2). All embodiments of the Suzuki invention are described as two-layer tablets ('299, column 5 line 2, column 6 line 11, column 7 line 37, column 7 line 67, column 7, column 9 line 28), single layer tablets (column 8 lines 65-66), discs (column 7 line 5, column 9 line 60), or two layer granules (column 5 lines 3-5).

The adhesive layer of the Suzuki invention is made by compressing an amount of polymer powder with a punch, dice and press ('299 column 4 lines 47-54). The adhesive layer of the Suzuki invention having a property to swell in the presence of water, may gradually disintegrate and disappear or "it can be removed with force from where it adheres...When it swells up enough, it can be removed easily with the tip of a finger or anything like a spatula" ('299, column 3, lines 46-52). The preparation of the Suzuki invention is basically a medication delivery patch that can be attached on wet mucous membranes and skin. The term "preparation" is overly broad and misleading as used in the Suzuki patent.

The present invention discloses methods for enhancing penetration of compounds/drugs into hair follicles. The composition of the present invention "is a form of ointment, cream, lotion, gel, spray, tonic, mousse, paste and the like" (specification, page 8 lines 20-21). The composition is applied to skin areas having hair follicles where drug penetration is desired. A key feature of the composition of the present invention is that it penetrates into the hair follicles (claim 1) and with light massage penetrates into the inner lumen of the hair follicles (specification, page 12, lines 5-7). The preparation of the Suzuki '299 patent can not penetrate a hair follicle. The two inventions are clearly different.

The Suzuki '299 patent neither anticipates nor makes obvious the present invention.

Claims 1-2, 4-5, 10-20 stand rejected under 35 U.S.C 103 (a) as being unpatentable over Suzuki et al. (U.S. Patent No. 4,292,299) in view of Schaefer et al. (U.S. Patent No. 5,292,512).

The examiner is correct that Suzuki teaches a medical preparation containing an adhesive layer and non-adhesive layer to be administered to wet mucous surfaces and skin. The examiner is also correct that Schaefer teaches the use of microspheres containing active products for topical application.

The examiner argues that it would have been obvious to one having ordinary skill in the art to use microspheres in the preparation of Suzuki's "preparation" because they would want to target specific regions for treatment as opposed to simply applying the topical application and risking secondary effects on nearby follicular channels.

In order to have secondary effects on the nearby follicular channels, the adhesive layer in Suzuki's preparation would have to be able to flow into the follicles. This is not foreseeable. As previously described, the preparation of the Suzuki patent can best be described as a medicated patch. The adhesive layer is press formed from a powder and a medication containing nonadhesive layer is placed thereon. ('299 column 4 lines 52-57). The so-called preparation is then attached to a wet mucous surface for delivery of a medicament. The adhesive layer is solid enough to support the nonadhesive layer. It does not have sufficient flow properties to enter a follicular channel.

Schaefer et al. teaches the use of a composition containing microspheres of polymers filled with an active product, characterized in that at least 80% of the microspheres have a diameter between 3  $\mu\text{m}$  and 10  $\mu\text{m}$ . An object of the '512 patent is to select the size of the microspheres so as to promote their selective entry into the sebaceous follicles ('512 column 2, lines 29-31).

It would not be obvious to one having ordinary skill in their respective arts to combine the teachings of Schaefer and Suzuki. Even if one considered the teachings of Schaefer, which would be to use large microspheres in the Suzuki adhesive layer to prevent it from entering the follicular channels would not be obvious or necessary.

Conversely, the teaching of swellable polymer adhesives as taught in Suzuki would not be considered by those having ordinary skill in the art described by Schaefer. The key teaching of Schaefer is that the use of a specific size range of microspheres (diameters between 3  $\mu\text{m}$  and 10  $\mu\text{m}$ ) can promote their selective entry into the sebaceous follicles ('512 column 2, lines 29-31). Schaefer does teach the use of swellable polymers to prepare the described microspheres, prior to addition of an active compound, but any

swelling after the addition of the active compound and prior to entry in the follicular channel would prevent achievement of the inventive discovery expressed in Schaefer. In order to control the depth of entry into the sebaceous follicles the size of the microspheres must substantially be within a fixed, controlled range. It would be obvious to one having ordinary skill in the art that swellable microspheres would be counterproductive.

The addition of Schaefer et al. to Suzuki et al. does not disclose nor make obvious the present invention as described in the specification and now claimed.

Addressing the examiners response to applicants arguments filed 10/19/01:

The examiner is incorrect that the wet mucous surface and skin described by Suzuki is the same as external skin containing hair follicles. The skin described by Suzuki has a wet mucous layer, such as the lining of the mouth. The term skin, as defined by common usage, and used in the present invention, is the outer layer of epithelium that covers the body and that is exposed to the environment, such as skin on the arm, leg or face

The examiner responds that the Suzuki teaches the use of polymer that swells, and that it is inherent that such swelling action is physical, but the examiner is incorrect that such action would exert pressure on the follicle and that it would prevent follicle collapse. The adhesive layer in Suzuki, as previously described, is press formed from a polymer powder. It would not flow into a follicular channel where swelling could exert pressure on the follicle. All swelling would take place above the surface of the wet mucous membrane.

Regarding the examiners response to applicants prior 35 USC 103(a) arguments:

Applicant has previously stated that in Schaefer no swelling activity is described which takes place after the microsphere compound is applied to the skin. The examiner states that Schaefer clearly teaches using a polymer capable of swelling and that one with ordinary skill would be motivated to use a swelling polymer as taught by Suzuki within the microsphere when it is applied to the skin. This conclusion is in error. If the microspheres used in Schaefer were made of a water swellable polymer as taught by Suzuki, the microsphere size could not be controlled after application to the skin. As previously described in the present reply, the key invention of Schaefer is the discovery that by using

microspheres having a narrow range of diameters (3-10 microns) one could control the distribution of the microspheres (and active product contained therein) within the follicular channel. Swelling of the microspheres after application would increase the range of diameters and prevent the desirable controlled introduction of the active product into the follicular channel. There would be no motivation for one of ordinary skill in the art to employ a swellable polymer microsphere. Schaefer concerns itself with microspheres of known size range. The intentional use of swellable microspheres in follicular channels is unique to the present invention.

The addition of Schaefer et al. to Suzuki et al. does not disclose nor make obvious the present invention as described in the specification and now claimed.

In view of these remarks reconsideration is respectfully requested. An early and favorable response is earnestly solicited. Thank you.

Respectfully submitted,



Albert L. Robitaille, JD

Reg. No. 36,906

for:

Bolesh J. Skutnik, PhD, JD

Reg. No. 36,347

Attorney for Applicants

Fax: (413) 525-0611

Dated: April 26, 2002

CeramOptec Industries, Inc.  
515 Shaker Road  
East Longmeadow, MA 01028  
Phone: (413) 525-8222



RECEIVED

MAY 03 2002

TECH CENTER 1600/2580

BJA254bra

CERTIFICATION OF MAILING BY EXPRESS MAIL

The undersigned hereby certifies that this document was delivered to the United States Post Office in Manchester, Connecticut 06045 between 9:00 a.m. and 6:00 p.m. as Express Mail on April 26, 2002. The undersigned further declares that this Certification is made with the knowledge that willful false statement are punishable by fine or imprisonment, or both, under applicable sections of United States law and that willful false statements made before the United States Patent and Trademark Office may jeopardize the validity of the application or of issuing patents related thereto.

Albert L. Robitaille, JD

Express Mail No. ET909242644US